UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF TEXAS

HEALTH CARE SERVICE CORPORATION, a MUTUAL LEGAL RESERVE COMPANY	§	
	§	**CIVIL ACTION NO. _____**
Plaintiff,	§	
vs.	§	
EFREN OLIVARES, RICK BURCH, PHARMACIA & UPJOHN, INC., and PFIZER, INC.	§	
Defendants.	§	**JURY TRIAL DEMANDED**

PLAINTIFF'S COMPLAINT

I. NECESSITY OF ACTION

1. Health Care Service Corporation, a Mutual Legal Reserve Company operating through its divisions including Blue Cross Blue Shield of Texas ("HCSC") seeks damages resulting from Defendants' conduct concerning the sale and marketing of the drugs Geodon, Lyrica, and Zyvox.

2. Defendants' deceptive marketing practices and other improper conduct violated federal and state law and caused health plans to reimburse for prescriptions that Defendants knew had not been approved by the FDA. Defendants also improperly inflated demand for the drugs by false statements and omissions through the mails, the internet, and in person. Defendants' conduct has adversely affected HCSC. HCSC acts as a payor for millions of participants' pharmaceutical prescriptions pursuant to their respective health plans. Defendants' improper conduct caused HCSC to pay for an inflated number of participants' prescriptions, and other related health costs, for Geodon, Lyrica, and Zyvox as well as other associated health costs.

3. In May of 2004, Pfizer, Inc. ("Pfizer") entered into a corporate integrity agreement ("CIA") with the Office of the Inspector General of the United States Department of Health and Human Services to promote compliance with regulations and written directives of Medicare, Medicaid, all other federal health care programs, and other applicable statutes, regulations, and written directives of the FDA. Pfizer had agreed to enter into the CIA as part of the settlement it reached with the United States concerning Pfizer's off-label promotion of Neurotonin. In addition to the CIA, Pfizer had agreed to pay more than $430 million to resolve criminal charges in connection with its illegal and fraudulent promotion of unapproved uses of Neurotonin.

4. Despite Pfizer's history with Neurotonin, United States federal prosecutors later alleged that Pfizer engaged in similar off-label marketing behavior with respect to a number of other drugs, including Geodon, Lyrica, and Zyvox. Pfizer has settled the claims involving Geodon, Lyrica, and Zyvox with the United States Federal Government. Pfizer has also settled similar claims with at least 42 state governments. In September of 2009, a settlement agreement was announced between the United States and Pfizer. It was soon thereafter that payors such as HCSC began to understand the fraud and invective behavior of some of the Pfizer agents with relation to marketing of various drugs.

5. The United States alleged that with respect to **Geodon**, an atypical antipsychotic, from January 1, 2001 through December 31, 2007, Pfizer 1) promoted Geodon for off-label uses including: depression, bipolar maintenance, mood disorder, autism, and post-traumatic stress disorder; 2) promoted Geodon off-label to patients for which it had not received approval, including pediatric and adolescent patients; 3) promoted Geodon off-label for unapproved doses; 4) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Geodon; and 5) made and/or disseminated unsubstantiated and/or false

representations or statements about the safety or efficacy of Geodon. Crim. Settlement Agreement at 4 (a true and correct copy of the Criminal Settlement Agreement is attached as Exhibit "A"). The federal government alleged that Pfizer knowingly caused false or fraudulent claims for Geodon to be submitted to, or caused purchases by, Medicaid, Medicare, and other Federal Health Care Programs. *Id.* **Pfizer paid $301,462,065.00 to settle these claims.** Side Letter Agreement at 14 (hereby attached as Exhibit "B").

6. The United States alleged that with respect to **Lyrica**, an anti-epileptic, from September 1, 2005 through October 31, 2008, Pfizer 1) illegally promoted the sale and use of Lyrica for a variety of off-label conditions including chronic pain, neuropathic pain, and migraines; 2) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Lyrica including claims that it was superior to Neurotonin and its generic equivalent, gabapentin; and 3) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Lyrica. Exhibit A. at 5. The federal government alleged that Pfizer knowingly caused false or fraudulent claims for Lyrica to be submitted to, or caused purchases by, Medicaid, Medicare, and other Federal Health Care Programs. *Id.* **Pfizer paid $48,223,886.00 to settle these claims.** Exhibit B.

7. The United States alleged that, with respect to **Zyvox**, a synthetic antibacterial agent, from January 1, 2001 through February 28, 2008, Pfizer 1) promoted the sale and use of Zyvox for a variety of off-label conditions including infections caused by MRSA generally rather than those types of conditions for which Zyvox was FDA approved; 2) made and/or disseminated unsubstantiated and/or false representations about the safety efficacy of Zyvox including that Zyvox was superior to vancomycin; and 3) offered and pail illegal remuneration to health care professionals to promote and prescribe Lyrica. Exhibit A at 4-5. The federal government

alleged that Pfizer knowingly caused false or fraudulent claims for Zyvox to be submitted to, or caused purchases by, Medicaid, Medicare, and other Federal Health Care Programs. *Id.* **Pfizer paid $97,945,019.00 to settle these claims.** Exhibit B.

8. Although Pfizer has settled its litigation with the United States, third party payors have not received any compensation to date for the damages incurred due to Defendants' deceptive practices with regards to these three drugs. HCSC now brings its claims against Defendant for damages related to improper sales and marketing of Geodon, Lyrica, and Zyvox.

II. PARTIES

A. Plaintiff

9. Plaintiff HCSC processes **millions of claims** for some of its major national and mid-market accounts serviced out of **Marshall, Texas**. HCSC operates through its divisions, including Blue Cross Blue Shield of Texas, Blue Cross Blue Shield of Illinois, Blue Cross Blue Shield of New Mexico, and Blue Cross Blue Shield of Oklahoma. HCSC is organized under the laws of Illinois and its headquarters and principal place of business is in Chicago, Illinois. HCSC provides health coverage and third party administrative services for insureds, health plan members, and health plans. HCSC paid millions of dollars for Geodon, Lyrica, and Zyvox. Defendants improperly marketed and sold the drugs at issue and, as a result of Defendants' illegal and wrongful conduct, HCSC has suffered damages and Defendants have improperly profited.

B. Defendants

10. Defendant Efren Olivares was the national head of Geodon marketing and disseminated information encouraging and directing Pfizer's sales force to promote Geodon for off-label

purposes. Olivares can be served in New York, New York, but his current street address is unknown.

11. Defendant Rick Burch was a Senior Vice President at Pfizer. During his tenure with Pfizer, Burch lead the Arthritis, Pain and Metabolics Division. Amongst his duties, Burch planned and launched Lyrica, which he would later describe as the "most successful pharmaceutical launch of the year." Burch also "lead the U.S. integration of Pharmacia into Pfizer," during his tenure. Burch can be served in person at New York, New York, but his current street address is unknown.

12. Defendant Pfizer is a Delaware corporation with its principal place of business in New York. Pursuant to 28 U.S.C. § 1332(c)(1), Pfizer is considered a citizen of Delaware and New York. Defendant Pharmacia & Upjohn, Inc. ("Pharmacia") is a Delaware corporation with its principal place of business in New Jersey. Pursuant to 28 U.S.C. § 1332(c)(1), Pharmacia is considered a citizen of both Delaware and New Jersey. At all relevant times, Pharmacia has been engaged in the business of marketing and selling Bextra. In 2003, Pfizer acquired Pharamcia for nearly $60 billion. During the relevant time period, Pfizer has been engaged in the business of marketing and selling Geodon, Lyrica, and Zyvox nationwide. Defendants can be served through their registered agents for service, CT Corporation at 350 N. St. Paul Street, Suite 2900, Dallas, Texas 75201.

III. JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a). Complete diversity of citizenship exists between the Plaintiff and Defendants. The amount in controversy well exceeds $75,000. This Court also has federal question jurisdiction pursuant to the RICO statute. This Court has personal jurisdiction over Defendants, which are licensed to conduct

and/or systematically and continuously conducted business in Texas, including marketing, advertising and selling drugs (such as Geodon, Lyrica, and Zyvox) to residents in this State and via mails and internet to patients, doctors, payers, and drug representatives in the Eastern District of Texas as well as nationwide.

14. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a), because Defendants engaged in substantial conduct relevant to Plaintiff's claims within this District and caused harm to Plaintiff within this District. Pharmacia, Pfizer, and its agents did substantial business in this State and within the Eastern District of Texas, and at all times relevant hereto, Defendants developed, manufactured, promoted, marketed, distributed, tested, warranted, and/or sold in interstate commerce the aforementioned prescription drugs Geodon, Lyrica, and Zyvox.

IV. FACTUAL BACKGROUND OF GEODON

15. HCSC alleges that Defendants engaged in a marketing strategy for Geodon comprised of forms of the following three deceptive acts: 1) off-label marketing; (2) dissemination of misleading information regarding the respective drug's safety and efficacy; and (3) payment of improper remuneration or inducements to health care professionals to influence them to promote and prescribe these drugs. HCSC alleges that Defendants engaged in these deceptive acts in order to maximize prescriptions and ultimately reimbursements from payers including HCSC. The misconduct related to Geodon resulted in HCSC incurring damages related to increased health costs and reimbursements.

A) The Nature of Geodon

16. Geodon (the trade name for ziprasidone) belongs to a class of drugs traditionally used to treat schizophrenia. Drugs in this class are commonly referred to as "atypical antipsychotics." Geodon is the trade name for the atypical antipsychotic agent, ziprasidone.

17. Geodon treats bipolar and schizophrenia. But the specific mechanism of action is unknown. It has been proposed that Geodon's action against symptoms of schizophrenia involves a combination of dopamine type 2 and serotonin type 2 antagonism.[1]

18. Geodon, and other second-generation antipsychotics were developed to reduce the risks associated with first-generation antipsychotics and first-generation psychotics' potential to produce the following dangerous side effects: weight gain, hyperglycemia, diabetes, cardiovascular complications, and other severe complications

19. While Geodon arguably reduces one of the dangerous side effects associated with first generation antipsychotics—weight gain—Geodon does have side effects. It can cause "QT Prolongation." QT prolongation is an electrical disturbance of the heart muscle under which the heart muscle requires a longer than normal time to recharge or repolarize between beats.[2] Specifically, Geodon may induce prolongation of the QT interval of the PQRST wave on an electrocardiogram of the heart.[3]

20. QT prolongation as a result of ingesting Geodon may be fatal if sudden cardiac arrest is induced by ventricular rhythm disturbances.[4]

B) Geodon and the FDA

21. Geodon received initial approval by the United States Food and Drug Administration ("FDA") on February 5, 2001 for the treatment of acute manifestations of schizophrenia. Geodon was subsequently approved for the following limited uses as well:

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[1] https://www.pfizerpro.com/sites/ppro/pages/product_info/geodon_pi_clinical_pharmacology.as.

[2] http://www.mayoclinic.com/health/longqtsyndrome/DS00434/DSECTION=Causes.

[3] http://www.dddmag.com/news-Pfizer-Pays-2-Billion-to-Settle-Off-Label-Marketing-Case-090209.aspx.

[4] http://www.bio-medicine.org/medicine-news-1/Pfizer-Pays-a-Record-Amount-to-Settle-Federal-and-StateFraud-Investigations-Into-Illegal-Off-Label-Marketing-Practices-56020-2.

(1) June 21, 2002*:* Approved for acute agitation in schizophrenic patients for whom treatment with ziprasidone is inappropriate and who need intramuscular antipsychotic medication for rapid control of the agitation.

(2) August 19, 2004: Approved for acute manic or mixed episodes in Bipolar I disorder, with or without psychotic features

(3) March 29, 2006: Approval of Geodon for oral suspension for the treatment of schizophrenia and for the treatment of acute manic or mixed episodes associated with bipolar disorder, with or without psychotic features.

22. Approval for Geodon was the end of a long struggle for Pfizer. It involved reliance on clinical research done by scientists who had been or would be sanctioned and was, in the end, more limited than Pfizer had hoped.

(1) *Pfizer's struggle for Geodon's approval*

23. Geodon's initial FDA approval on February 5 marked the end of a long battle for Pfizer to obtain permission to market the drug. Pfizer had originally applied for approval of the drug under the name Zeldox in March, 1997. However, the FDA, because of concerns regarding Zeldox initiating serious arrhythmias, issued a "non-approvable letter" in 1998.

24. In 1998, when the FDA advisory committee rejected Zeldox, they asked Pfizer to conduct additional studies to assess the problems with QT prolongation and the arrhythmogenic potential of the drug. Two years later, Pfizer brought back the same drug to the FDA committee for re-evaluation and hoped for approval.

25. Pfizer re-applied to the FDA for approval of Zeldox in 2000. The FDA directed Pfizer to change the drug's name to avoid confusion between Zeldox and Zyvox (linezolid), an antibiotic medication. Pfizer renamed the drug Geodon and resubmitted an NDA without changing the drug's chemical components.

26. This second time, the FDA Advisory Committee approved Geodon over strong objections by FDA staff fearing its effects on the heart, including QT prolongation. Pfizer conceded the QT

interval problem, but argued it should be approved because it does not cause weight gain, an argument rejected by concerned FDA staff.

27. In fact, the NDA documents indicated that weight gain of greater than 7% was observed in 10% of subjects taking Geodon in the short-term placebo controlled phase II/III studies, and this was shown to be statistically significant when compared to a placebo.

(2) *Pfizer utilized reports by scientists who would later be sanctioned.*

28. Three physicians who contributed to the Geodon NDA for submission to the FDA have been disciplined for misconduct.[5]

29. Dr. Richard Borison, a psychiatrist, conducted many Geodon clinical trials and was debarred by the FDA. He was prohibited from either participating in or supervising any clinical drug trials for at least ten years. Convicted of embezzlement and research fraud, Dr. Borison is currently serving a minimum 15-year jail sentence.[6]

30. Dr. Bruce Diamond, a psychologist and pharmacologist, was debarred by the FDA and prohibited from participating in or providing services to any clinical trials for at least ten years. Convicted of research misconduct and embezzlement, he served time in prison.[7]

31. Dr. Louis Fabre, a psychiatrist who supervised some of the clinical Geodon trials, was sanctioned for research misconduct by the Texas Board of Medical Examiners.[8]

32. Pfizer's use of such clinical researchers demonstrates the lengths to which the company would go to facilitate its "positive" clinical trials' reporting and its subsequent scheme to market Geodon off-label as safe and effective while downplaying its known and dangerous side-effects.

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[5] http://industry.bnet.com/pharma/10004419/pfizer-used-docs-accused-of-misconduct-to-prep-geodon-submission-to-fda/?tag=content;selector-perfector.

[6] *Id.*

[7] *Id.*

[8] *Id.*

33. For example, the data presented by Pfizer to the FDA Advisory Committee incorrectly and misleadingly identified the adverse events associated with Geodon. A Pfizer employee reported that ziprasidone clinical trial data of adverse events reports ("AERs") with a frequency greater than 5% only included somnolence, respiratory infections, and possibly asthenia and insomnia. The Pfizer representative omitted important increases in neurologically associated adverse events including FPS/akathisia from his discussion—information that would have been known to him from Pfizer-sponsored, short-term clinical trials.

34. This Pfizer representative also misleadingly brought forth information suggesting that Geodon had favorable effects on serum cholesterol, LDL cholesterol and "especially triglycerides."

35. In fact, Pfizer went so far as to claim that '[Geodon] is an effective and well- tolerated treatment for a severe illness, and in contrast with the adverse effects of many other approved treatments, [Geodon] has "*'favorable effects' on well-documented cardiovascular risk factors."* This statement is intentionally misleading. It is, in part, the byproduct of clinical trial manipulation in which individuals who are switched from other antipsychotics to Geodon may experience a decline in certain lipid levels because there was a heightened increase with other drugs—not because there were any inherently favorable effects on cardiovascular risk factors without that design artifact. The statement is also misleading because it implies that taking Geodon may favorably improve cardiovascular risk factors simply by taking the drug, a statement that does not have reliable and reproducible scientific underpinnings and is contradicted by Pfizer's clinical trials submitted to the FDA for initial approval of the drug.

(3) *The limits of Geodon's approval*

36. Geodon has never been approved for the treatment of either Bipolar or schizophrenia for individuals not between the ages of eighteen and forty-five. And, while Geodon has been approved for treatment of either Bipolar or schizophrenia, it has not been approved solely to treat some of the symptoms that accompany these conditions such as anxiety and agitation.

C) Pfizer's marketing of Geodon

37. HCSC alleges that Pfizer coordinated deceptive off-label marketing and promotional practices for Geodon. Specifically, Pfizer devised and *successfully* implemented a marketing campaign calculated to increase primary care physicians' and psychiatrists' off-label use of Geodon—in various doses to treat symptoms, mood disorders, and patients within age demographics for which the drug has not received FDA approval (the elderly and pediatrics), nor which have been supported by medical studies. In increasing physicians' off-label uses of Geodon, Pfizer hoped to maximize ill-gotten profits and inflate total reimbursements from third-party payors, such as HCSC.

38. A key component of Pfizer's unlawful marketing of Geodon has been its claim that the drug is as safe or more effective than other antipsychotics and/or more tolerable and because of Geodon's comparatively "safe" metabolic profile. Pfizer claimed that patients prescribed to atypical antipsychotics should be switched to Geodon.

39. However, Pfizer's marketing of Geodon as comparatively safe and effective is deceptive and misleading and has materially minimized and/or concealed Geodon's dangerous side effects, in particular cardiovascular side effects such as the risks of heart attack and death from treatment-emergent QT prolongation.

40. Pfizer implemented its marketing strategy through the following deceptive practices.

(1) *Promotion of Geodon through an army of child psychiatrists for risky, unapproved pediatric population*

41. Even though Geodon is FDA approved only for patients from 18 to 45 years of age, sales team members encouraged administering Geodon in unapproved pediatric and adolescent populations.

42. Psychiatrist Dr. Stefan Kruszewski witnessed off-label promotion of Geodon for children by Pfizer sales representatives as well as by physicians receiving Pfizer kickbacks. The number of child psychiatrists maintained on the Pfizer payroll has been described as an "army of more than 250 child psychiatrists nationwide."[9] Pediatric psychiatrists were even paid generous fees to address their peers in lectures promoting Geodon.

43. Also, creating a 'Trojan Horse,' Pfizer funded the National Alliance for the Mentally Ill (NAMI), which suggested administering Geodon in the unapproved pediatric population on the NAMI website.[10] Administering Geodon in the unapproved pediatric population is particularly risky because children have a unique physiological makeup, and the safety of Geodon on this patient population had not been established.[11]

(2) *Promotion of Geodon for off-label treatments and uses*

44. Pfizer also employed a marketing scheme aimed at persuading prescribing physicians, including psychiatrists, primary care physicians and doctors of internal medicine, to use Geodon to treat the following conditions and symptoms—none of which were FDA-approved uses and none of which are medically accepted: agitation, depression, anxiety, personality disorders, psychotic symptoms not part of schizophrenia or Bipolar 1, sundowning, mood instability,

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9 http://philly. com/philly/business/56844147.html?viewAll=y

10 http://industry.bnet.com/pharma/10004316/pfizer-turned-nami-into-trojan-horse-to-push-geodon-off-label-to-kids-suit-claims/

11 http://www.bio-medicine.org/ medicine-news-1/Pfizer-Pays-a-Record-Amount-to-Settle-Federal-and-State-Fraud-Investigations-Into-Illegal-Off-Label-Marketing-Practices-56020-2/

impaired concentration, impaired attention, impulsivity, oppositional behaviors, irritability, delirium, dementias, sleeplessness, explosiveness and, finally, drug-induced excitement or withdrawal.

45. Also, Pfizer aggressively promoted Geodon to primary care physicians, internists, psychiatrists (geriatric, adult and child) for the treatment of depression. Treatment of depression is not a medically accepted indication of Geodon; it is off-label and not supported.

46. According to psychiatrist Stefan Kruszewski, Pfizer sales members 'pushed' him to prescribe Geodon for many unapproved symptoms, including, but not limited to, anxiety and agitation.[12]

47. Less than 5% of the United States population is diagnosed with schizophrenia or bipolar disorder. Therefore, it is particularly noteworthy that Geodon sales in 2008 nonetheless exceeded a billion dollars stemming not only from on-label marketing but also from the illegal practice of off-label marketing.[13]

48. Off-label marketing was done at the direction of management. For instance, at one National Sales Meeting held at the Disney Complex in Orlando Florida, Defendant Olivares, the national head of Geodon marketing, announced to the assembled Pfizer sales managers that Pfizer's goal was to grow the market for Geodon by promoting its use beyond the current market of schizophrenia. This meeting was attended by many of Pfizer's District Mangers, Regional Managers, and Vice Presidents in Pfizer's sales divisions. In this presentation, the Pfizer sales force was directed to promote Geodon for the following unapproved uses: 1) borderline personality disorder; 2) refractory mood disorders (depression, obsessive compulsive disorder,

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12 http://philly.com/philly/ business/56844147. html?viewAll=y

13 http://www.dddmag.com/news-Pfizer-Pays-2-Billion-to-Settle-Off-Label-Marketing-Case-090209.aspx

post traumatic stress disorder); 30 dementia in the elderly; 4) bipolar mania; 5)bipolar maintenance; and 6) pediatric/adolescent conduct disorders. This sales plan was put into practice in sales offices by district managers across the country, such as the district manager for Chicago.

49. Another instance is described by a qui tam complaint, in which Curt McAllister, a Regional Manager at Pfizer's Plan of Attack Meeting ("POA") in St. Louis, Missouri, actively encouraged sales representatives to promote Geodon at much higher doses than those approved by the FDA. This continued a trend for Pfizer of promoting to physicians at a dosage exceeding 160 mg a day in spite of Geodon's FDA approved label of 20 to 80 mg twice daily. Curt McAllister's correspondence and work files will reveal additional improper conduct by Pfizer and others.

50. In addition to actively promoting off-label dosages of Geodon, McAllister had knowledge of other off-label promotions by Pfizer's sales representatives. McAllister was made aware by a district manager that at least one sales representative refused to promote Geodon to doctors that used second generation antipsychotics for purposes for which Geodon was not indicated. Another sales representative reported to a District Manager and McAllister the promotion of off-label usage of Geodon to treat dementia in nursing homes in Oklahoma.

(3) *Promotion of Geodon as safe compared to competitor drugs*

51. When patients were already undergoing treatment with competitor atypical antipsychotics such as Zyprexa, Seroquel and Risperdal, Pfizer sales members urged physicians to switch patients to Geodon instead. Promoting Geodon as safer than the competitor atypical

antipsychotics is particularly egregious in light of Geodon's potentially life threatening side effects, particularly QT Prolongation.[14]

52. According to a qui tam complaint, Regional Manager Curt McAllister once sent almost 90 sales representatives a voice message telling them to use a "compare and win strategy" in which Geodon was compared to Abilify, a Bristol-Meyers Squibb product. McAllister was informed that this strategy was unsupported and in direct violation of Pfizer's compliance policy and FDA regulations; however, despite acknowledging this problem and promising a correction or retraction, a retraction from McAllister did not make it to a majority of the sales representatives for Geodon.

53. Pfizer has received a "Warning Letter" from the FDA directed at false and misleading promotional activities regarding safety claims for Geodon as well as non-approved indication for depression. This letter provided that: "Pfizer Inc. (Pfizer) has promoted Geodon in a manner that is misleading and lacking fair balance because it minimizes the important risk information regarding the greater capacity of Geodon to cause QT prolongation, and the potential to cause *torsade de pointes-type* arrhythmia and sudden death."

54. Pfizer-sponsored advertisements have misleadingly represented that Geodon has minimal ability to cause neurological side-effects, despite evidence to the contrary and evidence that was known to Pfizer prior to, at the time of, and after the re-submission of the NDA in 2000. In fact, Geodon produces neurological disorders known as extrapyramidal symptoms ("EPS") in a dose-dependent manner. EPS are anticipated in a substantial percentage of patients, perhaps as many as 30%, who take Geodon at the higher doses needed to produce reliable antipsychotic effects.

55. At least two Pfizer pharmaceutical representatives told Dr. Kruszewsk *that* they believe

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[14] http://www.dddmag.com/news-Pfizer-Pays-2-Billion-to-Settle-Off-Label-Marketing-Case-090209.aspx

that Pfizer knowingly misrepresents the risk of neurological side-effects caused by Geodon.

56. Also, Pfizer offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Geodon in violation of the Federal Anti-Kickback Statute.

D) Some legal consequences thus far

57. On or around September 2, 2009, forty-two states reached a settlement with Pfizer related to the alleged improper marketing of Geodon. While Pfizer did not formally acknowledge any wrongdoing with respect to its marketing of Geodon, the settlement agreement *mandated* that Pfizer:

(1) not make any false, misleading or deceptive claims regarding Geodon;

(2) not promote Geodon for off-label uses;

(1) not promote Geodon using selected symptoms of the FDA-approved diagnoses;

(2) post on its website a list of physicians and related entities who received payments from Pfizer until 2014;

(3) provide product samples of Geodon only to health care providers who have specialties that customarily treat patients who have diseases for which treatment with Geodon would be consistent with the product's current labeling;

(4) register clinical trials and submit results as required by federal law; register Geodon Pfizer-sponsored Phase II, III, and IV clinical trails ongoing or initiated after July 1, 2005; and post on a publicly accessible website all Pfizer-sponsored Phase II, III, and IV clinical trials completed after October of 2002; and

(5) require its medical staff to be responsible for the identification, selection, approval, and dissemination of article reprints containing off-label information regarding Geodon and that such information not be referred to or used in a promotional manner.

The settlement also mandated that for a nine-year period extending beyond the patent term of Geodon, Pfizer must:

(1) require its medical staff, rather than its marketing staff, to have ultimate responsibility for developing and approving the medical content for all medical letters regarding Geodon, including those that may describe off-label information. This information shall not be distributed unless certain criteria are met; and

(2) provide specific, accurate, objective, and scientifically balanced responses to unsolicited requests for off-label information regarding Geodon.

Finally, for a six-year period, Pfizer agreed to:

(1) disclose information about grants, including continued-medical-education grants, on its website, for a least two years and maintain the information for five years;

(2) not use grants to promote Geodon, or condition continued-medical-education funding on Pfizer's approval of speakers' of the program content; and

(3) contractually require continuing-medical-education providers to disclose Pfizer's financial support of their programs and any financial relationship with faculty and speakers.

V. FACTUAL BACKGROUND OF LYRICA

58. Defendants engaged in a marketing strategy for Lyrica involving improper and deceptive acts including: 1) off-label marketing; (2) dissemination of misleading information regarding the respective drug's safety and efficacy; and (3) payment of improper remuneration to health care professionals to induce them to promote and prescribe these drugs. Defendants engaged in these deceptive acts in order to obtain inflated prescriptions and reimbursements from payers.

A) The Nature of Lyrica

59. Lyrica is the trade name for Pregabalin. It is an anti-epileptic. While the exact mechanism of action is unknown, Lyrica likely reduces the quantity of electrical signals originating from damaged or overexcited nerves.[15]

60. Pfizer developed Lyrica as the successor to another epilepsy drug: Neurotonin.[16] It even called Lyrica the "Son of Neurontin." *Id.* At the time, Pfizer faced falling stock values and data linking some of its other lucrative drugs to heart attacks. In developing a successor to

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15 http://lyrica. com/main_how_lyrica_works.aspx

16 http://.www.boston.com/yourlife/health/diseases/articles/2005/01/01/fda_oks_pfizers_drug_for_nerve_pain/

Neurotonin, Pfizer hoped to capture at least a portion of Neurotonin's success. *Id.* In 2003, Neurotonin achieved $2.2 billion in sales. Pfizer's improper promotion of Neurotonin ultimately lead to a $430 million settlement with United States to settle off-label allegations brought by the U.S. Attorneys in Boston.

B) Lyrica and the FDA

61. Lyrica received FDA approval; yet the approval was more limited than Pfizer had hoped and also revealed Lyrica's limits and side effects. The FDA approved marketing Lyrica for the treatment of four conditions:

(1) neuropathic pain resulting from postherpetic neuralgia ("PHN") on Dec. 31, 2004 (www.deadiversion.usdoj.gov/fed_regs/rules/2005/fr0728. htm);

(2) neuropathic pain resulting from diabetic peripheral neuropathy ("DPN") on Dec. 31, 2004 (www.deadiversion.usdoj.gov/fed_regs/rules/2005/ fr0728.htm);

(3) partial onset seizures as adjunct therapy in adults treated with one or more anti-seizure medications on June 10, 2005 (https://www.caremark. com/portal/asset/PipelineJune24.pdf)(http://www.medscape.com/viewarticle/506781) ; and

(4) fibromyalgia-induced muscle pain on June 21, 2007. (U.S. Food and Drug Administration (June 21, 2007). ("FDA Approves First Drug for Treating Fibromyalgia" Press Release)

62. The FDA declined to approve Lyrica for treating anxiety disorders. The FDA classified Lyrica as a controlled substance subjecting it to Drug Enforcement Agency (DEA) regulations thus making it more difficult to prescribe than Neurontin.[17]

63. Furthermore, designated a Schedule V controlled substance, Lyrica may be habit-forming with potential for misuse similar to Valium due to euphoric effects.[18] In studies with recreational users of sedative/hypnotic drugs, about 4% of subjects noted euphoria as an adverse event versus

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17 http://www.mmm-online.com/setback-for-pfizer-drug-lyrica/article/22504/

18 http://www.regencerx.com/docs. consumerRx/lyrica.pdf

1% for placebo with some sub-populations indicating euphoria rates up to 12%. It follows that patients receiving Lyrica should be monitored to prevent dependence, misuse, or abuse.[19]

C) The Marketing of Lyrica

(1) *Description of deceptive practices*

64. In an effort to replicate its success with Neurotonin, Pfizer illegally promoted the sale and use of Lyrica for multiple off-label conditions. Some of these unapproved indications include chronic pain, neuropathic pain, perioperative pain, and migraine.

65. Moreover, Pfizer created and disseminated unsubstantiated/false representations pertaining to Lyrica's safety and efficacy. Among these misrepresentations were the assertions that Lyrica was superior to Neurontin as well as its generic equivalent, gabapentin. For instance, at one POA held in Cedar Rapids, Iowa, a District Manager instructed the sales force in attendance to promote Lyrica's efficacy compared to gabapentin and to tout Lyrica as a "better agent" than gabapentin. These instructions from the District Manager were made despite the absence of any adequate, well-controlled head-to-head, clinical study comparing Lyrica to gabapentin.

66. Sales team members received training to practice "Pfizer Math" to persuade health care professionals that head-to-head comparisons with the drugs Keppra and Neurontin demonstrated Lyrica's superiority when such data was nonexistent and such studies had not been performed.[20] In other instances, Pfizer's sales representatives were given "Compare and Win" marketing materials that compared the drugs' efficacy and bioavailability and claimed that Lyrica's effects onset quicker than gabapentin.

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[19] http://www.centerwatch.com/drug-information/fda-approvals/drug-details.aspx?DrugID=900

[20] http://industry.bnet.com/pharma/10004284/pfizer-math-showed-lyrica-superiority-even-though-studies-never-said-that-rep-claims/

67. After Lyrica was introduced to the market, sales representatives were further instructed to tout Lyrica's alleged superiority to gabapentin "at any cost."

68. In order to induce health care professionals to promote and prescribe Lyrica, Pfizer made offers of and payments of illegal remuneration (kickbacks).

69. As with many of Pfizer's other drugs, Pfizer instructed its sales force to manipulate medical inquiry requests regarding off-label uses from doctors. The FDA prohibits the unsolicited dissemination of information promoting the off-label use of drug by a pharmaceutical manufacturer. However, a pharmaceutical manufacturer may provide information concerning off-label uses of a drug in some instances when it receives an inquiry as to an off-label use from a physician. Pfizer took advantage of this exception by generating responses to phony medical inquiry requests in order to promote Lyrica for off-label uses.

70. During this time period, Pfizer engaged in the above described conduct to knowingly cause false/fraudulent claims for Lyrica to be submitted to Medicaid, Medicare, and other Federal Health Care Programs.

(2) *FDA Warning Letter confirms deceptive practices*

71. An FDA Warning Letter, discusses findings of the FDA monitoring and surveillance program. The Division of Drug Marketing, Advertising, and Communications (DDMAC) reviewed sponsored Pfizer links on internet search engines such as Google and listed seven links judged to be misleading involving seven medications. The FDA wrote:

> The sponsored links cited in this letter are misleading because they make representations and/or suggestions about the efficacy of Aromasin, Caduet, Chantix, Detrol LA, Lyrica, and Celebrex, but fail to communicate **any** risk information associated with the use of these drugs . . . . Furthermore, all of the sponsored links fail to use the required established name. Thus, the sponsored links misbrand the drugs in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and FDA implementing regulations. *See* 21 U.S.C. § 352(a) & (n), 321(n); 21 CFR 201.10(g)(1), 202.1(b)(1), (e)(3)(i), (ii) & (e)(6)(i).

In other words, the sponsored links misbranded the medications by omitting the requisite established names and by discussing efficacy in a vacuum without discussing risk.

72. Omitting risk information equates to providing misleading information because "for promotional materials to be truthful and non-misleading, they must contain risk information in each part as necessary to qualify any claims made about the drug . . . . By omitting the most serious and frequently occurring risks associated with the drugs promoted in the links . . . the sponsored links misleadingly suggest that . . . (the drugs) are safer than has been demonstrated."

> Promotional materials, other than reminder pieces, which include the name of the drug product but do not include indications or other representations or suggestions relative to the drug product (see 21 CFR 200.200, 201.100(f), 202.1(e)(2)(i)), are required to disclose risk and other information about the drug. Such materials are misleading if they fail to reveal facts that are material in light of the representations made by the materials or with respect to consequences that may result from the use of the drug as recommended or suggested by the materials.

Nor does merely including a product website link in the sponsored link rectify the omission.

73. Misbranding violates the Federal Food, Drug, and Cosmetic Act along with FDA implementing regulations (21 U.S.C. §§ 352(a) & (n), 321(n); 21 CFR §§ 201.10(g)(1), 202.1(b)(1), (e)(3)(i), (ii) & (e)(6)(i). Hence, the FDA Warning Letter directed Pfizer to immediately cease the dissemination of violative promotional materials for Aromasin, Caduet, Chantix, Detrol LA, Lyrica and Celebrex and to review other "promotional materials for the other prescription drug products that Pfizer promotes in the United States and to discontinue or revise any materials with the same or similar violations. . . ." Finally, the FDA Warning Letter notes that the mentioned violations do not constitute an exhaustive list such that it is Pfizer's

responsibility to review and modify promotional materials as needed to ensure compliance with the FDCA and with FDA implementing regulations.[21]

D) Some legal consequences thus far

74. The Defendants have not directly settled any claims with third party payors relating to Lyrica. However, as part of Defendant's Bextra plea agreement with the United States, the United States released its claims involving Lyrica. For Lyrica, the United States' claims asserted: 1) off-label promotion; 2) false representations regarding efficacy; and 3) illegal kickbacks to health care professionals. Crim. Settlement Agreement at 4–5.

VI. FACTUAL BACKGROUND OF ZYVOX

75. Zyvox is the trade name for linezolid, a synthetic antibacterial agent. Pharmacia received FDA approval for Zyvox on April 18, 2000. The FDA approved Zyvox for the treatment of bacterial infections such as infections due to methicillin-resistant *Staphylococcus aureus* ("MSRA") including nocosomial pneumonia (hospital-acquired pneumonia) and complicated skin and skin structure infections ("CSSSIs") caused by MRSA.

76. As a reserve antibiotic for the treatment of infections caused by Gram-positive bacteria that are resistant to other antibiotics, Zyvox should not be used against bacteria that are sensitive to drugs with a narrower spectrum of activity and should be used only for treating infections proven or strongly suspected to be caused by susceptible bacteria. Further, Zyvox should be administered sparingly to protect its reserve antibiotic role as a drug of last resort effective

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21 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM143487.pdf

against potentially intractable infections and to minimize the development of drug-resistant bacteria.[22]

77. Although no studies demonstrated by substantial evidence that Zyvox exhibited superior efficacy over its primary competitor, vancomycin, Pfizer promoted it as such. In addition, Zyvox was eight times more expensive than vancomycin. This is true even though catheter patients experienced an eight percent greater mortality rate if treated with Zyvox versus another antibiotic.[23]

78. According to Neil Fishman, an infectious disease doctor at the Hospital of the University of Pennsylvania, Pfizer's marketing overstated benefits while minimizing potential problems. Dr. Fishman noted that less expensive medications could be utilized instead.[24]

79. Pfizer promoted Zyvox for a large number of off-label uses. In total, off-label promotions pushed Zyvox sales to exceed $1 billion.[25] The following provides a less than comprehensive list off the off-label promotions:

- Promoting Zyvox for the treatment of catheter related skin infections and concomitant bloodstream infections associated with catheter related skin infections.
- Promoting Zyvox for the treatment of surgical site infections or as a prophylaxis for the prevention of surgical site infections.
- Promoting Zyvox as effective for all infections caused by MRSA including community-acquired MRSA.

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22 http://media.pfizer.com/files/products/uspi_zyvox.pdf

23 http://industry.bnet.com/pharma/10004106/pfizer-rep-describes-pushing-zyvox-with-flawed-data/

24 http://philly.com/philly/business/56844147.html?viewAll=y

25 *Id.*

- Promoting Zyvox as an appropriate choice "anywhere on the treatment continuum" regardless of the infection.
- Promoting Zyvox as appropriate empiric therapy for all bacterial infections even though it has no effect on gram-negative infections and only partial effect on polymicrobial infections.

80. Regarding the safety and efficacy of Zyvox, Pfizer created and distributed unsubstantiated and false representations. To induce health care professionals to both promote and prescribe Zyvox, Pfizer offered and paid illegal remuneration.

81. The FDA sent Pfizer a Warning Letter regarding its marketing practices of Zyvox. The FDA determined that Pfizer's advertisements pertaining to Zyvox's superiority as compared to competitors had the potential to endanger public health.[26] The FDA Warning Letter objected to a journal advertisement making misleading and unsubstantiated implied superiority claims while omitting safety information (thus misbranding Zyvox). The FDA took exception to the discussion of retrospective analyses of head-to-head clinical trials of Zyvox and vancomycin by pointing out that these analyses were neither prospectively designed nor sufficiently powered to provide statistically significant differences in treatment groups. Consequently, Zyvox's superiority had not been demonstrated by substantial evidence. In addition to categorizing the advertisement in question as misbranding, the FDA Warning Letter ordered Pfizer to cease dissemination of the journal advertisement along with other promotional material making similar assertions.

82. Pfizer responded that it did not concur that the journal article made an improper superiority claim but nonetheless would cease use of that journal advertisement, review all

[26] http://philly.com/philly/business/56844147.html?viewAll=y

Zyvox promotional material for similar concerns, discontinue or revise promotional material that could potentially be misinterpreted in such a manner, and instruct its sales force to discontinue use of specified promotional materials. At the FDA's direction, Pfizer published a corrective advertisement entitled "IMPORTANT CORRECTION OF DRUG INFORMATION ZYVOX" acknowledging the FDA's objection to the advertisement presenting Zyvox more favorably than vancomycin noting data included on the Zyvox label stated that, in a clinically evaluable population, 57% of Zyvox patients and 60% of vancomycin patients were cured of MRSA and 59% (13/22) of Zyvox patients and 70% (7/10) of vancomycin patients with microbiologically-confirmed MRSA were clinically cured.

83. Pfizer and its executives failed to adequately inform the sales force of which statements should be discontinued concerning data from head-to-head trials and retrospective analyses. Consequently, Pfizer sales force personnel continued to promote to physicians the superiority of Zyvox over vancomycin in certain MRSA patients, and also claimed that Zyvox would produce a higher cure rate and save more lives.

84. In spite of knowledge of the FDA Warning Letter and associated issues, Pfizer executives and sales managers were not only aware of but also encouraged sales messages presenting Zyvox as superior to vancomycin for certain patients. In particular, a regional manager and a headquarters-based vice president participated in this ongoing misrepresentation.

85. Defendants' marketing strategy for Zyvox was uniquely dangerous. Despite Zyvox's role as a reserve antibiotic such that it is critical to prescribe it sparingly, sales members promoted it to physicians for various types of infections, including post-surgery infections for which there is no supporting data, and as being effective against bacteria for which it demonstrates little or no effect.

86. Pfizer's reckless promotion of Zyvox without regard to the issues pertinent to preserving its status as a reserve antibiotic also accelerated the proliferation of MRSA infections resistant to treatment with conventionally prescribed antibiotics. This conduct has increased health costs of Plaintiff.

87. The Defendants have not directly settled any claims brought by any third party payor relating to Zyvox. But, as part of Defendant's Bextra plea agreement with the United States, the United States released its claims involving Zyvox. For Zyvox, the United States' claims asserted: 1) off-label promotion; 2) false representations regarding efficacy; and 3) illegal kickbacks to health care professionals.

88. Plaintiff, as a third-party payor, has suffered damages as a result of Defendants' conduct. Plaintiff has paid for Zyvox for off-label uses for which it was not approved and for Zyvox when a safer more appropriate alternative was available.

VII. EQUITABLE AND LEGAL TOLLING

89. Plaintiff hereby pleads fraudulent concealment, equitable tolling, and the discovery rule. Defendants actively concealed the nature of their conduct from Plaintiff. Furthermore, such conduct was not of such a nature to have put on notice of its various disparate claims. Then-pending class actions also tolled the limitations period pursuant to state and federal law.

VIII. CLAIMS

90. HCSC incorporates by reference all preceding paragraphs as if fully set forth herein.

A) HCSC's First Claim for Relief: Illinois Consumer Protection Act[27]

91. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 Ill. Comp. Stat. § 510/2, *et seq.*

92. The unfair and deceptive acts and practices of Defendants have directly, foreseeably, and proximately caused or will cause damages and injury to HCSC.

93. The above described course of improper, fraudulent conduct and/or fraudulent concealment, constitute acts, uses, or employment by Defendants of unconscionable commercial practices, deception, fraud, false pretenses, misrepresentations and the knowing concealment, suppression or omission of material facts with the intent that others rely upon such concealment, suppression, or omission of material facts in connection with the sale of merchandise of Defendants in violation of Illinois law.

94. Specifically, these acts: caused likelihood of confusion or misunderstanding as to the goods' approval and certification (815 Ill. Comp. Stat. § 510/2(a)(2)); caused likelihood of confusion or misunderstanding as to the goods' certification by another (815 Ill. Comp. Stat. § 510/2(a)(3)); represented the goods as having sponsorship, approval, characteristics, uses, benefits, or quantities that they did not have (815 Ill. Comp. Stat. § 510/2(a)(5)); represented that these goods were of a particular standard, quality, or grade (815 Ill. Comp. Stat. § 510/2(a)(7)); disparaged the goods of another by false or misleading representation of fact (815 Ill. Comp. Stat. § 510/2(a)(8)); and engaged in various other forms of conduct that created a likelihood of

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[27] Although Plaintiff has numbered certain claims (e.g. fraud, negligence), there are more than one claim under each theory of liability. The unfair trade practices of marketing and selling Geodon, for example, is a separate claim from the unfair trade practices of marketing and selling Zyvox. Therefore, the total number of claims asserted in this action are over a dozen and Defendants' disclosures and discovery production will likely raise that number substantially depending on whether various marketing strategies were stand alone promotions or if they were one overarching "plan."

confusion or misunderstanding. (815 Ill. Comp. Stat. § 510/2(a)(12)).

95. HCSC relied on Defendants' deceptive trade practices. Defendants' deceptive trade practices caused HCSC to pay for its participants' prescriptions to these drugs for unapproved uses. By reason of the unlawful acts engaged in by Defendants, HCSC has suffered ascertainable loss and damages. As a direct and proximate result of Defendants' wrongful conduct, HCSC was damaged by paying for these prescriptions.

B) HCSC's Second Claim for Relief: Unjust Enrichment

96. To the detriment of HCSC, Defendants have been unjustly enriched as a result of the unlawful and/or wrongful collection of payments for Geodon, Lyrica, and Zyvox.

97. Accordingly, HCSC seeks full restitution of Defendants' enrichment, benefits, and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

C) HCSC's Third Claim for Relief: Common Law Fraud

98. Defendants intended that HCSC and the medical and scientific community would rely on their materially deceptive practices and that HCSC would pay for its participants' prescriptions for Geodon, Lyrica, and Zyvox as a consequence of the deceptive practices. With respect to these drugs, these deceptive practices included Defendants' (1) off-label marketing; (2) dissemination of misleading information regarding the respective drug's safety and efficacy; (3) omission of material information about the safety and approved uses of the respective drug; and (4) payment of improper remuneration to health care professionals to induce them to promote and prescribe these drugs.

99. Defendants' deceptive representations and material omissions to HCSC and the medical and scientific community were unfair and deceptive acts and practices. HCSC was deceived by Defendants' misrepresentations. And, as a proximate result of Defendants' misrepresentations,

HCSC has suffered an ascertainable loss, in an amount to be determined at trial, in that it paid tens of millions of dollars for the consequences of improper marketing of Geodon, Lyrica, and Zyvox (including increased drug reimbursements and medical costs for improperly minimized or completely undisclosed adverse effects, *interalia*) that it would not have paid had Defendants not engaged in unfair and deceptive conduct.

D) HCSC's Fourth Claim for Relief: Negligence and Negligence Per Se

100. The Defendants are liable to Plaintiff for negligence and negligence per se. Defendants undertook a duty to act as a reasonably prudent pharmaceutical company by disseminating information to physicians, health care providers, and health insurers, such as HCSC concerning Geodon, Lyrica, and Zyvox. Defendants knew that Plaintiff, and other insurers and third-party payors, were relying on the materials and information disseminated by Defendants in making a decision to place these drugs on Plaintiff's formularies. By distributing this information to physicians, health care providers, and insurers, Defendants undertook a duty to provide accurate information. Defendants violated this duty by engaging in off-label marketing by marketing these drugs for purposes other than those they were indicated for and received approval for from the FDA.

101. Defendants actions were also negligent per se. By marketing these drugs for uses other than those approved by the FDA, Defendants violated the provisions of the FDCA. 21 U.S.C. § 301, et seq.

102. As a result of Defendants' negligence, Plaintiff has suffered damages in that it has placed these drugs on its formulary and paid for these drugs for uses for which they were not approved. Plaintiffs were further injured because they paid more for these drugs when there were safer, cheaper, and more effective alternatives available. HCSC has suffered an ascertainable loss, in

an amount to be determined at trial, in that they paid millions for these drugs that they would not have paid had Defendants not engaged in negligent conduct.

E) HCSC's Fifth Claim for Relief: Conspiracy

103. Defendants, by acting in concert with one another, their various agents, and other physicians and entities engaged in multiple conspiracies to fraudulently promote and sell Geodon, Lyrica, and Zyvox for purposes for which they were not approved. The Defendants agreed to promote Geodon, Lyrica, and Zyvox in this fashion in order to maximize sales and profits from Geodon, Lyrica, and Zyvox that could not otherwise be achieved by marketing and selling Geodon, Lyrica, and Zyvox in compliance with the uses approved by the FDA.

104. Defendants engaged in conduct that has been described herein to distribute false and misleading information and communications concerning Geodon, Lyrica, and Zyvox to physicians, consumer, and third-party payors. The distribution of this information and communications caused Plaintiff to add Geodon, Lyrica, and Zyvox to its formulary and to pay for participants purchases of Geodon, Lyrica, and Zyvox.

105. Defendants' conduct caused Plaintiff to suffer damages, in an amount to be ascertained at trial, in that it has paid millions for Geodon, Lyrica, and Zyvox that it would have not paid in light of available cheaper and safer alternatives.

F) HCSC's Sixth Claim for Relief: Violations of 18 U.S.C. § 1962(c)

106. HCSC hereby alleges a claim against Defendants for violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c).

107. Plaintiff and Defendants are each "persons" as that term is defined in 18 U.S.C. § 1961(3).

108. At all relevant times, in violation of 18 U.S.C. § 1962(c), Defendants conducted the affairs of an association-in-fact enterprise identified herein, the affairs of which affected interstate commerce through a pattern of racketeering activity.

109. For purposes of this claim, the RICO "Enterprise" is an association-in-fact consisting of each of the Defendants, including the directors, employees, and agents that were not named as Defendants in this matter. The Enterprise also includes outside advertising agencies utilized by Defendants and the Medical Directors of Pfizer and Pharmacia. The Enterprise further includes any medical journal that entered into financial agreements to sell reprints of commercially advantageous articles about Geodon, Lyrica, and Zyvox. While maintaining their separate legal identities and titles, each of these entities and persons joined together to run the Enterprise. At all relevant times, the Enterprise was an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for common or shared purposes of (a) publishing or otherwise disseminating information about Geodon, Lyrica, and Zyvox, which was often false, misleading, and in violation of the FDCA, (b) jointly presenting data to the FDA and medical journals that is misleading and/or has been manipulated to distort the results of clinical trials, (c) promoting Geodon, Lyrica, and Zyvox in an attempt to force Plaintiff to add these drugs to its formulary, (d) achieving the goal of having these drugs replace other drugs, including traditional NSAIDs, that are safer and more effective, and (e) deriving profits from these activities beyond those that could have been attained without operation of the Enterprise. The Enterprise also directed a marketing blitz that targeted physicians whose usual patients had indications for which Defendants had not received FDA approval for marketing. The Enterprise had as a common purpose creating and perpetuating demand for Geodon, Lyrica, and Zyvox in a class of consumers that could have used lower-priced and safer drugs and

achieved the same, if not superior, results from the safer lower-cost drugs. Defendants had this purpose because without the scheme, they would not have been able to sell these drugs and achieve the economic benefits each obtained as a result of the operation of the Enterprise. During most of the time relevant to this complaint, each Defendant maintained a separate legal identity while operating the Enterprise, and others associated with and part of the Enterprise maintained their separate identities. Agents and members of the Enterprise include advertising agencies used to create advertisements and doctors who co-author articles promoting Geodon, Lyrica, and Zyvox. As to each Defendant, the association-in-fact met on a regular basis to discuss the operations of the Enterprise and the Enterprise's efforts were coordinated and agreed to by each Defendant.

110. Each of the members of the Enterprise had a systematic linkage, because there are contractual relationships, financial ties, and continuing coordination of activities between the Defendants and the Enterprise. As to each Defendant, there was a common communication network by which information concerning the Enterprise was exchanged on a regular basis. Typically this communication occurred by the use of electronic mail or the telephone, with which Defendants and their agents planned the operation of the Enterprise alleged herein and ran its continuing operation.

111. With the merger of Pfizer and Pharmacia, the Enterprise is now an association-in-fact consisting of individuals at Pfizer in charge of running the Enterprise with respect to Geodon, Lyrica, and Zyvox. The individuals include, and have included other sales executives in charge of marketing efforts, executives in charge of advertising, and those in charge of developing responses to safety issues.

112. At all relevant times, the Defendants were knowing participants in the Enterprise and benefited from its operation. The Defendants exerted control over the Enterprise and management of the affairs of the Enterprise.

113. The Enterprise engaged in and affected interstate commerce, because, *inter alia*, the deceptive and fraudulent activities described herein led to the marketing and sale of Geodon, Lyrica, and Zyvox to thousands of individuals and entities throughout the United States. The Enterprise distributed false and misleading information through the mail and by electronic mail directly to each other and to physicians and consumers across state boundaries. Defendants conducted and participated in the affairs of the Enterprise through patterns of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), and § 1952 (use of interstate facilities to conduct unlawful activity).

114. Defendants' use of the mails and wires to perpetuate their fraud involved numerous communications, including, but not limited to:

a. communications with and among Enterprise participants on marketing strategies for Geodon, Lyrica, and Zyvox that violated the FDCA;

b. communications with and among the Enterprise participants that fraudulently misrepresented the efficacy, safety, and uses of Geodon, Lyrica, and Zyvox amongst themselves and others;

c. communications directed at physicians, consumers, and payors, such as Plaintiff, including, but not limited to, payments for Geodon, Lyrica, and Zyvox by misrepresenting the efficacy, safety, and uses of these drugs;

d. receiving the proceeds in the course of an resulting from Defendants' improper scheme;

e. transmittal and receipt of monies from consumers and third-party payors, such as Plaintiff;

f. communications with and among the enterprise participants for the purpose of inducing doctors to be become high prescribers of Geodon, Lyrica, and Zyvox through various forms of illegal remuneration;

g. communications amongst the Defendants and others to promote head-to-head studies that either did not exist or did not conclude that Geodon, Lyrica, and Zyvox were superior to competitors drugs;

h. communications amongst the Defendants and others to provide information to medical journals designed to conceal the risks of Geodon, Lyrica, and Zyvox and falsely promote its safety and efficacy; and

i. communications to agencies of the United States government that deliberately concealed the risks, safety, and efficacy of Geodon, Lyrica, and Zyvox.

115. Many of the precise dates of Defendants' uses of the U.S. mails and interstate wires facilities have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Enterprise alleged herein depended upon secrecy, and as alleged above, Defendants took steps to deliberately conceal their wrongdoing.

116. Defendants motive for participating the Enterprise was to maximize profits from Geodon, Lyrica, and Zyvox. Defendants knew that without engaging in their Enterprise, consumers and third-payors, such as Plaintiff, would not have paid for Geodon, Lyrica, and Zyvox for the off-label uses that the Defendants promoted. Furthermore, consumers and third-payors would have used cheaper, safer, and more effective competing brands.

117. The conduct of the Defendants through their Enterprise described above constituted "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendants' decisions and activity in connection with the Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

118. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm the FDA, physicians, psychiatrist, the public, and third-party payors (such as Plaintiff). Each such racketeering activity was related, had similar purposes, involved similar or the same victims (consumers, physicians, third-party payors), including Plaintiff. Defendant's racketeering activities were part of their ongoing business and constitute a threat to the property of Plaintiff.

119. Plaintiff has been injured in its property by reason of these violations in that Plaintiff has paid millions of dollars for Geodon, Lyrica, and Zyvox that they would not have paid had Defendants not engaged in this pattern of racketeering activity.

120. The injuries to Plaintiff were directly and proximately caused by Defendants' racketeering activity.

121. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are liable to Plaintiff for three times the damages sustained, plus the coast of this suit, including reasonable attorney's fees.

IX. PRAYER

122. HCSC demands judgment against Defendants in each claim for relief, jointly and severally, as follows:

1. On Plaintiff's Consumer Protection Act claim, all measures of damages allowable under such statutes, including treble damages, such amount to

be determined at trial, plus Plaintiff's costs in this suit, including attorneys' fees;

2. On Plaintiff's common fraud claim, compensatory damages, punitive damages, such amounts to be determined at trial, plus Plaintiff's costs in this suit, including all reasonable attorneys' fees;

3. On Plaintiff's claim for unjust enrichment, recovery in the amount of Plaintiff's payments and/or Defendants' related profits for the drugs at issue, such amount to be determined at trial, plus Plaintiff's costs in this suit, including all reasonable attorneys' fees;

4. On Plaintiff's claim for negligence and negligence per se, recovery in the amount of Plaintiff's payments for the drugs at issue, such an amount to be determined at trial, plus Plaintiff's costs in this suit, including all reasonable attorneys' fees;

5. On Plaintiff's conspiracy claim, recovery in the amount of Plaintiff's payments for the drugs at issue, such an amount to be determined at trial, plus Plaintiff's costs in this suit, including reasonable attorney's fees;

6. On Plaintiff's RICO claim, all measure of damages allowable under the statute at issue including treble damages, such amount to determined at trial, plus Plaintiff's costs in this suit, including attorneys' fees;

7. Awarding Plaintiff other appropriate equitable relief;

8. Awarding Plaintiff its costs and expenses in this litigation, including reasonable attorneys' fees and expert fees; and

9. Awarding Plaintiff pre- and post-judgment interest on all actual damages, as well as such other and further relief as may be just and proper under the circumstances.

X. DEMAND FOR JURY TRIAL

123. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands trial by jury on all issues so triable.

Respectfully submitted,

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